DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 28 2000

The Honorable Michael Bilirakis
House of Representatives
Washington, D.C. 20515-0909

Dear Mr. Bilirakis:

Thank you for your letter of June 30, 2000, cosigned by four of your colleagues, regarding the Food and Drug Administration's (FDA or the Agency) September 1, 1999, Notice of Proposed Rulemaking (NPRM) which proposes to set the standard for determining when the use of an ozone-depleting substance (ODS) in a product regulated by the Agency is essential under the Clean Air Act.

Your letter expressed concern that under the NPRM, "a new CFC-containing MDI made with a currently marketed drug substance will be automatically deemed essential by FDA, even if that product offers no new important health benefit."

Your letter has been forwarded to Docket No. 97N-0023 for inclusion in the record of comment on the proposed rule. Your comments will be considered as FDA moves forward in the rulemaking process.

You may also be aware that during the Open-Ended Working Group (OEWG) from July 11 to 13, 2000, a "Draft Decision by the European Community on MDIs" was forwarded to the Parties to the Montreal Protocol for consideration. At the OEWG meeting, the United States delegation focused on listening to the concerns of members, on gathering information regarding the draft decision, and gaining clarity on the intent of the decision, including issues related to new CFC-based MDIs. The decision is to be revised by the European Community in response to concerns raised by other parties at the OEWG, and the revised draft decision will be on the agenda for the Meeting of the Parties in December 2000.

97N-0023

ANS 2

Your continuing interest in this issue is appreciated. If you have further questions, please let us know. A similar letter has been sent to your cosigners.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

cc: Dockets Management Branch
97N-0023